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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,823	12/01/2003	Ning-Sun Yang	08919-080001	3608
26161	7590	05/05/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			LEITH, PATRICIA A	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 05/05/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/725,823	<b>Applicant(s)</b> YANG ET AL.	
	<b>Examiner</b> Patricia Leith	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) 20-38 and 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-38 and 41-45 are pending in the application.

Claims 20-38 and 41-43 were withdrawn without traverse from examination on the merits as they are directed toward a non-elected invention (see previous Office Action).

Newly submitted claims 44 and 45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 44 and 45 are directed toward processes for making the extract of claim 1. The inventions are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case as evidenced by the claims themselves, the extract of claim 1 may be prepared by the addition of another percentage of alcohol not recited by claims 44 and 45. Note that claim 1 requires a range of alcohol percentages.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claims 44 and 45 are hereby withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-19 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

***Claim Rejections - 35 USC § 112***

Claims 1-6, 8-9, 11-12, 14-15 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

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“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.’ *Lockwood v. American Airlines, Inc.*, 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, no that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F. 3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient” MPEP § 2163.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus MPEP § 2163. Although the MPEP does not define what constitutes a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. *In Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 1-6, 8-9, 11-12, 14-15 and 17-18 are broad generic claims, with respect to *all possible* extracts from any species of *Dioscorea*. The possible variations of extracts (i.e., their inherent phytochemical constituents) are limitless to any extract which meets the limitations of being soluble in water and insoluble in an aqueous solution containing varying amounts of ethanol between certain temperatures. The specification lacks sufficient variety of extracts of species of the *Dioscorea* genus to reflect this variance in since the specification does not provide any other examples of extracts besides *D*.

*batatas* which provide for the claimed characteristics. This is further evidenced by the fact that *Dioscorea* genus comprises around 500 species (see University of Florida internet site, page 1).

*The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.*

See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

Claims 1-7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hikino et al. (JP 61106516 A, English Abstract).

Hikino et al. (JP 61106516 A, English Abstract) disclosed the aqueous extract of the rhizome (tuber) *Dioscorea batatas* (common name; yam) (see English abstract). It is deemed that the water extract of *D.batatas* would be insoluble in an aqueous solution

containing 65-90% ethanol at the claimed temperatures, especially absent evidence to the contrary.

Applicants admit that Hikino et al. disclose the extract of *D.batatas* which is insoluble in 80 – 80.57% ethanol and assert that the most recent amendment which states 50% - 75% and 65%-75% overcomes this reference. However, it is deemed that the extract which was disclosed by Hikino et al. would inherently contain all ethanol insoluble matter from less than 1% to 80.57% ethanol. In other words, extracts which are insoluble in 50% - 75% or 65%-75% ethanol, will inevitably be present in an extract performed with 80 –80.57% ethanol because the less insoluble matter will precipitate with the higher amount (80- 80.57%) of alcohol added to the water extract of *D.batatas*.

Because Applicant's invention is inherent to Hikino et al, it is deemed that the composition disclosed by Hikino et al. would also provide for the function of enhancing the proliferation of bone marrow or spleen cells.

Claims 8-10 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Pei-Fen et al. (2001).

Pei-Fen et al. (2001) disclosed extracts from Chinese yam (aka *D.batatas*) which were combined with IL-2 for enhancing proliferation of Tcells for example (Tcells are bone marrow cells because they are found in bone marrow).



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pei-Fen et al. (2001).

The teachings of Pei-Fen et al. were discussed *supra*. Pei-Fen et al. did not specifically discuss that the extracts of Chinese yam were insoluble in 50%-75%, 65% - 75% or 65% - 90% ethanol.

Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966) (Claims to the free-flowing crystalline form

of a compound were held unobvious over references disclosing the viscous liquid form of the same compound because the prior art of record did not suggest the claimed compound in crystalline form or how to obtain such crystals.).

It is deemed that the active ingredient which displays enhancement of splenocytes was present in the ethanol-insoluble extracts of Chinese yam as disclosed by Pei-Fen et al. Thus, it was already known in the art that the ethanol-insoluble portion of the water extract of *D.batatas* contained the active ingredient. One of ordinary skill in the art would have been motivated to further elucidate (purify) the active ingredient in order to create a substantially pure product free of non-actives. This would have been especially useful for properly diluting the active ingredient to varying dosage forms and eliminating unwanted side effects of other endogenous ingredients.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith  
Primary Examiner  
Art Unit 1655

A handwritten signature in black ink, appearing to read "Patricia Leith", written in a cursive style.

April 25, 2006